Reviewer's report

Title: Feasibility and results of a randomised pilot-study of pre-discharge occupational therapy home visits

Version: 2 Date: 22 January 2007

Reviewer: Rob de Haan

Reviewer's report:

This manuscript aims to describe the feasibility of an RCT to test the effect of pre-discharge home visits in older people undergoing rehabilitation.

Major compulsory revisions
In the last paragraph of the Introduction the authors should explicitly state that the primary aim of the study is the investigate the feasibility, whereas the secondary aim is to explore possible treatment effects. With regard to the efficacy analyses, I also advice the authors to stress (both in the Introduction and in the Discussion section) the importance of collecting pilot data so that - in the preparation of a future full-scale trial - an appropriate choice for a primary outcome parameter can be made, including the need for data to perform a sound power-analysis.

In the Discussion section, the authors correctly raise point by point what they have learned from this pilot, and how to use this information in a future trial. However, in this section some methodological aspects deserve more attention.

First, the authors should discuss the methodological /ethical problem how to avoid Hawthorne effects in patients when informing them completely about the purpose of the study. Hence, unblinded patients who assess outcomes after being informed about the different treatment options during recruitment might bias the results of a study. The likelihood of bias increases when patients have a preference for one of the treatment options (see also BMJ 2003;327;284-285).

Second, it should be stressed that in the future trial the care (and control) treatment has to be delivered by a broad range of occupational therapists within a multi-centre design. Not only, to improve the generalizability of the findings, but also to ascertain that the outcomes of the treatment is the result of the specific characteristics of the care program, and not the result of some individual qualities of one or two care givers involved.

Third, point on the importance of using checklists to assure a standardized delivery of the care program.

The statistical paragraph is not completely clear. The repeated data structure in combination with the use of GLM suggest a repeated measurement analysis. Table 2, however, shows a between-group analyses on each time point. This suggests that the authors used ordinary linear regression adjusting for pre-treatment scores. Am I correct? Please, explain.

Minor essential revisions
Please, delete the p-values in Table 1. Assuming that the randomization was unbiased, baseline differences between treatment groups are per definition based on chances and as such p-values are redundant in this context.

Discretionary revisions
Background
Please delete in the in fourth paragraph the term (n=60), since this number does not say anything about the question whether the concerning study was (in)sufficiently powered.

Methods-outcome assessments
Please give additional information about the blinded assessor. What was his or her professional background? Was the assessor one of the authors?

Discussion
In the first paragraph the authors state that the study turned out to be feasible in terms of data analysis. Please delete this last remark as statistical analyses, if appropriately performed, are always feasible. You don’t need a pilot study to explore this issue.
What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:
I declare that I have no competing interests